UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: COVIDIEN HERNIA MESH PRODUCTS LIABILITY LITIGATION NO. II,	
This Document Relates To:	**MDL No. 1:22-md-03029-PBS**
All Cases	**Hon. Patti B. Saris**

DEFENDANTS COVIDIEN LP AND SOFRADIM PRODUCTION SAS'S ANSWER AND AFFIRMATIVE DEFENSES TO PLAINTIFFS' MASTER LONG FORM COMPLAINT

Pursuant to Case Management Order No. 7, Defendants Covidien LP ("Covidien") and Sofradim Production SAS ("Sofradim") (collectively, "Defendants") hereby submit their Answer and Affirmative Defenses to the Master Long Form Complaint ("Complaint") propounded by Plaintiffs on February 13, 2023. Defendants deny each and every allegation in the Complaint except those expressly admitted below.

Answering the introductory paragraphs of the Complaint, Defendants state that Case Management Order No. 7 and the Complaint speak for themselves, and any attempt to characterize or draw implications or inferences inconsistent with their explicit text is denied.

I. PARTIES

1. Subject to Defendants' response to paragraph 19 of the Complaint, Defendants admit that some of their hernia mesh products are listed in paragraph 19 of the Complaint and that Plaintiffs refer to those devices collectively as "Hernia Mesh Devices" or "Devices" in the

Complaint. Defendants are without knowledge or information sufficient to admit or deny the remaining allegations in paragraph 1, specifically whether Plaintiffs are men and women implanted with one or more of Defendants' Hernia Mesh Devices to repair their hernias, and therefore deny the same.

2. Paragraph 2 states a legal conclusion to which no response is required. To the extent a response is required, Defendants admit only that Plaintiffs refer to spouses and others with purported standing to assert claims arising from and/or damages resulting from certain Hernia Mesh Devices as "Consortium Plaintiffs." Defendants are without knowledge or information sufficient to admit or deny Consortium Plaintiffs' relationship to Plaintiffs, and therefore deny the same. Defendants deny the remaining allegations in paragraph 2, specifically that any claims arose from and/or damages resulted from their hernia mesh products.

3. Responding to footnote 2, Defendants state that CMO No. 6 speaks for itself, and any attempt to characterize or draw implications or inferences inconsistent with its explicit text is denied. Responding to paragraph 3, Defendants do not understand what is meant by "substantial" in this context and cannot properly respond to this allegation. Defendants admit that Covidien is a Delaware limited partnership with its principal place of business at 15 Hampshire Street, Mansfield, Massachusetts 02048. Defendants further admit that at certain times Covidien has researched, developed, tested, manufactured, produced, marketed, promoted, and sold medical devices, including certain hernia mesh products. Defendants further admit that at certain times Covidien has derived revenue related to certain Hernia Mesh Devices sold in the United States. Defendants deny the remaining allegations in paragraph 3.

4. Defendants admit that at certain times, Covidien designed, manufactured, and sold certain Hernia Mesh Devices in the United States. Defendants deny the remaining allegations in

paragraph 4, specifically the vague references to "initially manufactured" and "first placed the Hernia Mesh Devices on the market from its headquarters in Massachusetts."

5. Defendants admit that at certain times certain Covidien employees in Massachusetts corresponded with the U.S. Food & Drug Administration ("FDA") in relation to certain Hernia Mesh Devices. Defendants deny the remaining allegations in paragraph 5.

6. Defendants deny the allegations in paragraph 6.

7. Defendants admit that Sofradim is a French company with its principal place of business at 116 Avenue du Formans, Trevoux, France. The remaining allegations state legal conclusions to which no response is required. To the extent a response is required, Defendants deny the remaining allegations in paragraph 7. Defendants further deny any wrongdoing or that their products were defective or injured Plaintiffs.

8. Defendants admit that prior to its acquisition by Covidien plc, Sofradim was a wholly owned subsidiary of Floreane Medical Implants, S.A., a French corporation. Defendants deny the remaining allegations in paragraph 8.

9. Defendants admit that Sofradim and its parent and affiliates were indirectly wholly owned by Covidien plc. Defendants further admit that there is a Sofradim facility in Trevoux that is involved in the manufacturing of surgical devices. Defendants also state that Sofradim is registered with the FDA, Covidien is listed with the FDA, the FDA registrations speak for themselves, and any attempt to characterize or draw implications or inferences inconsistent with their explicit text is denied. Defendants deny the remaining allegations in paragraph 9.

10. Defendants do not understand what is meant by "substantial" in this context and cannot properly respond to this allegation. Defendants deny the allegations in paragraph 10.

11. Defendants admit that Plaintiffs refer to named Defendants collectively as "Defendants" in the Complaint starting at paragraph 11, which does not require a response from Defendants. The allegations in the next four sentences of paragraph 11 state legal conclusions to which no response is required. To the extent a response is required, Defendants state that their Hernia Mesh Devices are safe and effective, and Defendants have always complied with any and all legal duties to which they may be subject. Responding to the last sentence of paragraph 11, Defendants deny the remaining allegations.

12. Defendants deny the allegations in paragraph 12.

13. Defendants do not understand what is meant by "training" and cannot properly respond to this allegation. Defendants state that at certain times, one or both Defendants were engaged in the design, manufacture, production, testing, study, research, inspection, labeling, marketing, advertising, sales, promotion, and/or distribution of certain Hernia Mesh Devices, and that at certain times, marketing, promotion, and sale occurred in Massachusetts and throughout the United States. Defendants deny the remaining allegations in paragraph 13.

14. Defendants do not understand what is meant by "substantial" in this context and cannot properly respond to this allegation. Defendants incorporate their responses to paragraphs 3 and 10 as to revenue related to certain Hernia Mesh Devices sold in the United States. Defendants deny the remaining allegations in paragraph 14.

15. Defendants deny the allegations in paragraph 15.

II. JURISDICTION AND VENUE

16. Paragraph 16 states legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in paragraph 16.

17. Paragraph 17 states legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in paragraph 17.

18. Defendants lack information sufficient to admit or deny whether any of the alleged acts and transactions giving rise to Plaintiffs' causes of action occurred in the federal judicial district identified in Plaintiffs' Short Form Complaints. The remaining allegations in paragraph 18 state legal conclusions to which no response is required. To the extent a response is required, Defendants deny the remaining allegations in paragraph 18.

III. FACTS COMMON TO ALL COUNTS

19. Defendants admit that Plaintiffs have defined Hernia Mesh Devices as hernia meshes designed, manufactured, marketed, labeled, distributed, sold, or otherwise placed on the market, including but not limited to the 19 related devices listed and described in paragraph 19. [1] Defendants admit that at certain times, one or both of them have designed, manufactured, marketed, labeled, distributed, and sold one or more of the devices listed in paragraph 19. Defendants state that the website referenced in footnote 3 speaks for itself, and any attempt to characterize or draw implications or inferences inconsistent with its explicit text is denied. Defendants deny the remaining allegations in paragraph 19.

20. Defendants admit that Hernia Mesh Devices are cleared by the FDA under Section 510(k) of the Food, Drug, and Cosmetic Act ("FDCA"), which speaks for itself. Any attempt to characterize or draw implications or inferences inconsistent with Section 510(k)'s explicit text in paragraph 20 is denied. Defendants deny the remaining allegations in paragraph 20, specifically

[1] Defendants further state that one or more of the hernia mesh products listed in paragraph 19 are identified inconsistently with their names as trademarked and marketed.

the vague allegation that "no formal review for safety or efficacy was ever conducted for the Hernia Mesh Devices."

21. Defendants admit that at certain times, one or both Defendants designed, manufactured, produced, tested, studied, inspected, labeled, marketed, advertised, sold, promoted, and distributed certain Hernia Mesh Devices. The remainder of paragraph 21 states a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the remaining allegations in paragraph 21.

22. Defendants deny the allegations in paragraph 22.

23. The first sentence of paragraph 23 states legal conclusions to which no response is required. To the extent a response is required, Defendants state that they have always complied with any and all legal duties to which they may be subject. Defendants deny the remaining allegations in paragraph 23.

24. Defendants deny the allegations in paragraph 24.

25. Defendants state that the websites referenced in footnotes 4, 5, 6, and 7 speak for themselves, and any attempt to characterize or draw implications or inferences inconsistent with their explicit text is denied. Defendants deny the remaining allegations in paragraph 25.

26. Defendants deny the allegations in paragraph 26.

27. Defendants admit they have marketed certain Hernia Mesh Devices in accordance with the Instructions for Use but deny they have directly marketed devices to Plaintiffs and deny the remaining allegations in paragraph 27.

28. Defendants deny the allegations in paragraph 28.

29. Defendants deny the allegations in paragraph 29.

30. Paragraph 30 states a legal conclusion to which no response is required.

31. Defendants state that the Safety Medical Devices Act of 1990 speaks for itself, and any attempt to characterize or draw implications or inferences inconsistent with its explicit text in paragraph 31 is denied.

32. Paragraph 32 states a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations in paragraph 32.

33. Defendants deny the allegations in paragraph 33.

34. Defendants deny the allegations in paragraph 34.

35. Defendants deny the allegations in paragraph 35.

36. Defendants deny the allegations in paragraph 36.

37. Defendants deny the allegations in paragraph 37.

38. Defendants deny the allegations in paragraph 38.

39. Defendants deny the allegations in paragraph 39.

40. Defendants deny the allegations in paragraph 40.

41. Defendants deny the allegations in paragraph 41.

42. Defendants deny the allegations in paragraph 42.

43. Defendants deny the allegations in paragraph 43.

44. Defendants deny the allegations in paragraph 44.

45. Defendants admit that at certain times, Covidien marketed and sold certain Hernia Mesh Devices to doctors and hospitals. Defendants deny the remaining allegations in paragraph 45.

46. Defendants deny the allegations in paragraph 46.

47. Defendants admit that the devices categorized by the Complaint as "Bare Polymer Hernia Mesh Devices" contain polyester or polypropylene. Defendants deny the remaining allegations in paragraph 47.

48. Answering paragraph 48 and its footnote, Defendants admit that several of the Bare Polymer Hernia Mesh Devices, as defined in this Complaint, are multifilament.

49. Defendants state that the literature referenced in footnote 9 speaks for itself, and any attempt to characterize or draw implications or inferences inconsistent with its explicit text is denied. Defendants deny the remaining allegations in paragraph 49.

50. Defendants state that the literature referenced in footnote 10 speaks for itself, and any attempt to characterize or draw implications or inferences inconsistent with its explicit text is denied. Defendants deny the remaining allegations in paragraph 50.

51. Defendants deny the allegations in paragraph 51 and its subparts.

52. Defendants deny the allegations in paragraph 52.

53. Defendants deny the allegations in paragraph 53.

54. Defendants deny the allegations in paragraph 54.

55. Defendants deny the allegations in paragraph 55.

56. Defendants deny the allegations in paragraph 56.

57. Defendants deny the allegations in paragraph 57.

58. Defendants deny the allegations in paragraph 58.

59. Defendants are without knowledge or information sufficient to admit or deny the allegations in paragraph 59, and therefore deny the same.

60. Defendants deny the allegations in paragraph 60.

61. Defendants deny the allegations in paragraph 61.

62. Defendants deny the allegations in paragraph 62.

63. Defendants deny the allegations in paragraph 63.

64. Defendants admit that Parietex Composite Parastomal Mesh, Parietex PCO, Parietex PCOx, Parietex Composite Ventral Patch, Symbotex, and Parietene DS Composite Mesh have a resorbable collagen adhesion barrier. Defendants further state that the Instructions for Use referenced in footnote 11 speak for themselves, and any attempt to characterize or draw implications or inferences inconsistent with their explicit text is denied. Defendants deny the remaining allegations in paragraph 64 and footnote 11.

65. Defendants deny the allegations in paragraph 65.

66. Defendants deny the allegations in paragraph 66. Defendants further refer Plaintiffs to the Instructions for Use for Hernia Mesh Devices with an adhesion barrier for more information about the adhesion barrier.

67. Defendants deny the allegations in paragraph 67.

68. Defendants deny the allegations in paragraph 68.

69. Defendants admit that the collagen layer is hydrophilic, but deny the remaining allegations in paragraph 69.

70. Defendants deny the allegations in paragraph 70.

71. Defendants deny the allegations in paragraph 71.

72. Defendants deny the allegations in paragraph 72.

73. Defendants deny the allegations in paragraph 73.

74. Defendants admit some Resorbable Collagen Barrier Devices contain PGLA Expanders, but deny the remaining allegations in paragraph 74.

75. Defendants deny the allegations in paragraph 75.

76. Defendants deny the allegations in paragraph 76.

77. Defendants deny the allegations in paragraph 77.

78. Defendants admit that the PGLA Expanders are hydrophilic, but deny the remaining allegations in paragraph 78.

79. Answering paragraph 79 and footnote 12, Defendants admit that some Polymer Hernia Mesh Products Coated with Resorbable Collagen Barriers, as defined in this Complaint, are multifilament.

80. Defendants state that the literature referenced in footnote 13 speaks for itself, and any attempt to characterize or draw implications or inferences inconsistent with its explicit text is denied. Defendants deny the remaining allegations in paragraph 80.

81. Defendants deny the allegations in paragraph 81.

82. Defendants state that the literature referenced in footnote 14 speaks for itself, and any attempt to characterize or draw implications or inferences inconsistent with its explicit text is denied. Defendants deny the remaining allegations in paragraph 82.

83. Defendants state that the literature referenced in footnote 15 speaks for itself, and any attempt to characterize or draw implications or inferences inconsistent with its explicit text is denied. Defendants deny the remaining allegations in paragraph 83.

84. Defendants deny the allegations in paragraph 84.

85. Defendants state that the referenced Instructions for Use speak for themselves, and any attempt to characterize or draw implications or inferences inconsistent with their explicit text is denied. Defendants deny the remaining allegations in paragraph 85.

86. Defendants deny the allegations in paragraph 86.

87. Defendants deny the allegations in paragraph 87.

88. Defendants deny the allegations in paragraph 88.

89. Defendants deny the allegations in paragraph 89.

90. Defendants deny the allegations in paragraph 90.

91. Defendants deny the allegations in paragraph 91.

92. Defendants deny the allegations in paragraph 92.

93. Defendants deny the allegations in paragraph 93.

94. Defendants deny the allegations in paragraph 94.

95. Defendants deny the allegations in paragraph 95.

96. Defendants deny the allegations in paragraph 96.

97. Defendants deny the allegations in paragraph 97.

98. Defendants deny the allegations in paragraph 98.

99. Defendants deny the allegations in paragraph 99.

100. Defendants deny the allegations in paragraph 100.

101. Defendants admit that certain PLA Microgrip Devices—"Parietex ProGrip, Parietene ProGrip, and ProGrip [Laparoscopic]"—have PLA Microgrips. Defendants deny the remaining allegations in paragraph 101 and footnote 16.

102. Defendants deny the allegations in paragraph 102.

103. Defendants deny the allegations in paragraph 103.

104. Defendants admit that some of the products the Complaint refers to as "PLA Microgrip Devices" are hydrophilic, but deny the remaining allegations in paragraph 104.

105. Defendants deny the allegations in paragraph 105.

106. Defendants state that the cited guidelines and endorsements speak for themselves, and any attempt to characterize or draw implications or inferences inconsistent with their explicit text is denied. Defendants deny the remaining allegations in paragraph 106.

107. Defendants deny the allegations in paragraph 107.

108. Defendants deny the allegations in paragraph 108.

109. Defendants deny the allegations in paragraph 109.

110. Defendants deny the allegations in paragraph 110.

111. Defendants state that the referenced Instructions for Use speak for themselves, and any attempt to characterize or draw implications or inferences inconsistent with their explicit text is denied. Defendants deny the remaining allegations in paragraph 111.

112. Defendants state that the referenced Instructions for Use speak for themselves, and any attempt to characterize or draw implications or inferences inconsistent with their explicit text is denied. Defendants deny the remaining allegations in paragraph 112.

113. Defendants state that the referenced Instructions for Use speak for themselves, and any attempt to characterize or draw implications or inferences inconsistent with their explicit text is denied. Defendants deny the remaining allegations in paragraph 113.

114. Defendants deny the allegations in paragraph 114.

115. Defendants deny the allegations in paragraph 115.

116. Defendants deny the allegations in paragraph 116.

117. Paragraph 117 states a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations in paragraph 117.

118. Defendants deny the allegations in paragraph 118.

119. Defendants deny the allegations in paragraph 119.

120. Defendants deny the allegations in paragraph 120.

121. Defendants deny the allegations in paragraph 121.

IV. COUNTS

COUNT I
STRICT PRODUCT LIABILITY: DEFECTIVE DESIGN

122. Defendants incorporate by reference their answers to each allegation as set forth in preceding paragraphs as if fully stated herein.

123. Defendants deny the allegations in paragraph 123.

124. Defendants deny the allegations in paragraph 124.

125. Defendants deny the allegations in paragraph 125.

126. Defendants state that Covidien sold Hernia Mesh Devices with the intent that physicians and hospitals use the Devices in accordance with the Instructions for Use. Defendants deny the remaining allegations in paragraph 126.

127. Defendants are without knowledge or information sufficient to admit or deny the allegations in paragraph 127, and therefore deny the same.

128. Defendants deny the allegations in paragraph 128.

129. Defendants deny the allegations in paragraph 129.

130. Defendants deny the allegations in paragraph 130.

131. Defendants deny the allegations in paragraph 131.

132. Defendants deny the allegations in paragraph 132.

133. Defendants deny the allegations in paragraph 133.

134. Defendants deny the allegations in paragraph 134.

135. Defendants deny the allegations in paragraph 135.

136. Defendants deny the allegations in paragraph 136.

COUNT II
STRICT PRODUCT LIABILITY: FAILURE TO WARN

137. Defendants incorporate by reference their answers to each allegation as set forth in preceding paragraphs as if fully stated herein.

138. Defendants state that at certain times, one or both Defendants manufactured, distributed, and/or sold certain Hernia Mesh Devices. Defendants deny the remaining allegations in paragraph 138.

139. Defendants deny the allegations in paragraph 139.

140. Defendants deny the allegations in paragraph 140.

141. Defendants deny the allegations in paragraph 141.

142. Defendants deny the allegations in paragraph 142.

143. Defendants deny the allegations in paragraph 143.

144. Defendants deny the allegations in paragraph 144.

145. Defendants deny the allegations in paragraph 145.

146. Defendants state that Covidien sold Hernia Mesh Devices with the intent that physicians and hospitals use the Devices in accordance with the Instructions for Use. Defendants deny the remaining allegations in paragraph 146.

147. Defendants deny the allegations in paragraph 147.

148. Defendants deny the allegations in paragraph 148.

149. Defendants deny the allegations in paragraph 149.

150. Defendants deny the allegations in paragraph 150.

151. Defendants deny the allegations in paragraph 151.

152. Defendants deny the allegations in paragraph 152.

153. Defendants are without information or knowledge sufficient to admit or deny allegations regarding Plaintiffs' or Plaintiffs' physicians' state of mind, but deny the remaining allegations in paragraph 153.

154. Defendants deny the allegations in paragraph 154.

155. Defendants deny the allegations in paragraph 155.

156. Defendants deny the allegations in paragraph 156.

157. Defendants deny the allegations in paragraph 157.

158. Defendants deny the allegations in paragraph 158.

COUNT III
STRICT PRODUCT LIABILITY: MANUFACTURING DEFECT

159. Defendants incorporate by reference their answers to each allegation as set forth in preceding paragraphs as if fully stated herein.

160. Defendants deny the allegations in paragraph 160.

161. Defendants deny the allegations in paragraph 161.

162. Defendants deny the allegations in paragraph 162.

163. Defendants are without knowledge or information sufficient to admit or deny the allegations in the second sentence of paragraph 163, and therefore deny the same. Defendants deny the remaining allegations in paragraph 163.

164. Defendants deny the allegations in paragraph 164.

165. Defendants deny the allegations in paragraph 165.

166. Defendants deny the allegations in paragraph 166.

167. Defendants deny the allegations in paragraph 167.

168. Defendants deny the allegations in paragraph 168.

169. Defendants deny the allegations in paragraph 169.

COUNT IV
NEGLIGENCE

170. Defendants incorporate by reference their answers to each allegation as set forth in preceding paragraphs as if fully stated herein.

171. Paragraph 171 states a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations in paragraph 171.

172. Defendants deny the allegations in paragraph 172.

173. Defendants deny the allegations in paragraph 173 and its subparts.

174. Defendants deny the allegations in paragraph 174.

175. Defendants deny the allegations in paragraph 175.

176. Defendants deny the allegations in paragraph 176.

177. Defendants deny the allegations in paragraph 177.

178. Defendants deny the allegations in paragraph 178.

179. Defendants deny the allegations in paragraph 179.

180. Defendants deny the allegations in paragraph 180.

181. Defendants deny the allegations in paragraph 181.

COUNT V
NEGLIGENCE *PER SE*

182. Defendants incorporate by reference their answers to each allegation as set forth in preceding paragraphs as if fully stated herein.

183. Defendants deny the allegations in paragraph 183.

184. Paragraph 184 states a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations in paragraph 184.

185. Paragraph 185 states a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations in paragraph 185.

186. Defendants deny the allegations in paragraph 186.

187. Defendants deny the allegations in paragraph 187.

188. Defendants deny the allegations in paragraph 188.

189. Defendants deny the allegations in paragraph 189.

COUNT VI
GROSS NEGLIGENCE

190. Defendants incorporate by reference their answers to each allegation as set forth in preceding paragraphs as if fully stated herein.

191. Defendants deny the allegations in paragraph 191.

192. Defendants deny the allegations in paragraph 192.

193. Defendants deny the allegations in paragraph 193.

194. Defendants deny the allegations in paragraph 194.

195. Defendants deny the allegations in paragraph 195.

COUNT VII
STATE CONSUMER PROTECTION LAWS

196. Defendants incorporate by reference their answers to each allegation as set forth in preceding paragraphs as if fully stated herein.

197. Defendants are without knowledge or information sufficient to admit or deny the allegations in the first sentence of paragraph 197, and therefore deny the same. Defendants deny the remaining allegations in paragraph 197.

198. Defendants are without information or knowledge sufficient to admit or deny allegations regarding Plaintiffs' state of mind, but deny the remaining allegations in paragraph 198.

199. Defendants deny the allegations in paragraph 199.

200. Paragraph 200 states a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations in paragraph 200.

201. Defendants deny the allegations in paragraph 201.

202. Defendants deny the allegations in paragraph 202.

203. Paragraph 203 states a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations in paragraph 203.

204. Defendants deny the allegations in paragraph 204.

205. Defendants deny the allegations in paragraph 205.

206. Paragraph 206 states a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations in paragraph 206.

207. The second sentence of paragraph 207 states a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations in the second sentence of paragraph 207. Defendants deny the remaining allegations in paragraph 207.

208. Defendants deny the allegations in paragraph 208.

209. Defendants deny the allegations in paragraph 209.

210. Defendants deny the allegations in paragraph 210.

211. Defendants deny the allegations in paragraph 211.

COUNT VIII
BREACH OF IMPLIED WARRANTY

212. Defendants incorporate by reference their answers to each allegation as set forth in preceding paragraphs as if fully stated herein.

213. Defendants state that at certain times, Covidien sold certain Hernia Mesh Devices. Defendants are without information or knowledge sufficient to admit or deny the remaining allegations in paragraph 213, and therefore deny the same.

214. Defendants admit that at certain times, Covidien sold certain Hernia Mesh Devices to physicians, hospitals, and other healthcare providers for use in hernia repair surgeries, with the intent that physicians and hospitals use the product in accordance with the Instructions for Use. Defendants deny the remaining allegations in paragraph 214.

215. Paragraph 215 states a legal conclusion to which no response is required. To the extent a response is required, Defendants admit that at certain times, Covidien marketed certain Hernia Mesh Devices to physicians, hospitals, and other healthcare providers for use in hernia repair surgeries, with the intent that physicians and hospitals use the product in accordance with the Instructions for Use, and Defendants deny the remaining allegations in paragraph 215.

216. Defendants are without information or knowledge sufficient to admit or deny the allegations in paragraph 216, and therefore deny the same.

217. Defendants deny the allegations in paragraph 217.

218. Defendants deny the allegations in paragraph 218.

219. Defendants deny the allegations in paragraph 219.

COUNT IX
BREACH OF EXPRESS WARRANTY

220. Defendants incorporate by reference their answers to each allegation as set forth in preceding paragraphs as if fully stated herein.

221. Paragraph 221 states a legal conclusion to which no response is required. To the extent a response is required, Defendants admit that at certain times, Covidien marketed certain Hernia Mesh Devices to physicians, hospitals, and other healthcare providers for use in hernia repair surgeries, with the intent that physicians and hospitals use the product in accordance with the Instructions for Use, and Defendants deny the remaining allegations in paragraph 221.

222. Defendants are without information or knowledge sufficient to admit or deny the allegations in paragraph 222, and therefore deny the same.

223. Defendants are without information or knowledge sufficient to admit or deny the allegations in paragraph 223, and therefore deny the same.

224. Defendants deny the allegations in paragraph 224.

225. Defendants deny the allegations in paragraph 225.

226. Defendants deny the allegations in paragraph 226.

COUNT X
NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

227. Defendants incorporate by reference their answers to each allegation as set forth in preceding paragraphs as if fully stated herein.

228. Defendants deny the allegations in paragraph 228.

229. Defendants deny the allegations in paragraph 229.

230. Defendants deny the allegations in paragraph 230.

231. Defendants deny the allegations in paragraph 231.

COUNT XI
INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS

232. Defendants incorporate by reference their answers to each allegation as set forth in preceding paragraphs as if fully stated herein.

233. Defendants deny the allegations in paragraph 233.

234. Defendants deny the allegations in paragraph 234.

235. Defendants deny the allegations in paragraph 235.

COUNT XII
NEGLIGENT MISREPRESENTATION

236. Defendants incorporate by reference their answers to each allegation as set forth in preceding paragraphs as if fully stated herein.

237. Defendants deny the allegations in paragraph 237.

238. The first sentence of paragraph 238 states a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations in the first sentence of paragraph 238. Defendants deny the remaining allegations in paragraph 238.

239. Defendants admit that at certain times, Covidien marketed certain Hernia Mesh Devices to physicians, hospitals, and other healthcare providers for use in hernia repair surgeries, with the intent that physicians and hospitals use the product in accordance with the Instructions for Use. Defendants deny the remaining allegations in paragraph 239.

240. Defendants deny the allegations in paragraph 240.

241. Defendants deny the allegations in paragraph 241.

242. Defendants deny the allegations in paragraph 242.

243. Defendants deny the allegations in paragraph 243.

244. Defendants deny the allegations in paragraph 244.

245. Defendants deny the allegations in paragraph 245.

246. Defendants deny the allegations in paragraph 246.

COUNT XIII
FRAUD AND FRAUDULENT MISREPRESENTATION

247. Defendants incorporate by reference their answers to each allegation as set forth in preceding paragraphs as if fully stated herein.

248. Defendants state that at certain times, one or both Defendants designed, manufactured, marketed, and sold certain Hernia Mesh Devices. Defendants deny the remaining allegations in paragraph 248.

249. Defendants deny the allegations in paragraph 249.

250. Defendants state that at certain times, Covidien marketed certain Hernia Mesh Devices to physicians, hospitals, and other healthcare providers for use in hernia repair surgeries, with the intent that physicians and hospitals use the product in accordance with the Instructions for Use. Defendants deny the remaining allegations in paragraph 250.

251. Defendants state that at certain times, Covidien marketed certain Hernia Mesh Devices to physicians, hospitals, and other healthcare providers for use in hernia repair surgeries, with the intent that physicians and hospitals use the product in accordance with the Instructions for Use. Defendants deny the remaining allegations in paragraph 251.

252. Defendants state that at certain times, Covidien marketed certain Hernia Mesh Devices to physicians, hospitals, and other healthcare providers for use in hernia repair surgeries, with the intent that physicians and hospitals use the product in accordance with the Instructions for Use. Defendants deny the remaining allegations in paragraph 252.

253. Defendants deny the allegations in paragraph 253.

254. Defendants deny the allegations in paragraph 254.

255. Defendants deny the allegations in paragraph 255.

256. Defendants deny the allegations in paragraph 256.

257. Defendants deny the allegations in paragraph 257.

258. Defendants deny the allegations in paragraph 258.

COUNT XIV
FRAUDULENT CONCEALMENT

259. Defendants incorporate by reference their answers to each allegation as set forth in preceding paragraphs as if fully stated herein.

260. Defendants deny the allegations in paragraph 260.

261. Defendants deny the allegations in paragraph 261.

262. Defendants deny the allegations in paragraph 262.

263. Defendants deny the allegations in paragraph 263.

264. Defendants deny the allegations in paragraph 264.

265. Defendants deny the allegations in paragraph 265.

266. Defendants deny the allegations in paragraph 266.

267. Defendants deny the allegations in paragraph 267.

268. Defendants deny the allegations in paragraph 268.

269. Paragraph 269 states a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations in paragraph 269.

270. Paragraph 270 states a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations in paragraph 270.

271. Defendants deny the allegations in paragraph 271.

272. Defendants deny the allegations in paragraph 272.

273. Defendants deny the allegations in paragraph 273.

274. Defendants are without information or knowledge sufficient to admit or deny allegations regarding Plaintiffs' state of mind, but deny the remaining allegations in paragraph 274 that "Defendants' statements concerning their Hernia Mesh Devices were knowingly and intentionally false and misleading" and that "Defendants had not disclosed material facts and information to Plaintiffs or their health care providers that would have been material to the choice of treatment."

275. Defendants deny the allegations in paragraph 275.

276. Defendants deny the allegations in paragraph 276.

277. Defendants deny the allegations in paragraph 277.

278. Defendants deny the allegations in paragraph 278.

279. Defendants deny the allegations in paragraph 279.

280. Defendants deny the allegations in paragraph 280.

281. Defendants deny the allegations in paragraph 281.

282. Defendants deny the allegations in paragraph 282.

283. Defendants deny the allegations in paragraph 283.

COUNT XV
WRONGFUL DEATH

284. Defendants incorporate by reference their answers to each allegation as set forth in preceding paragraphs as if fully stated herein.

285. Paragraph 285 states a legal conclusion to which no response is required. To the extent a response is required, Defendants are without knowledge or information sufficient to admit

or deny on whose behalf or benefit Plaintiffs bring wrongful death claims, and therefore deny the same.

286. Defendants deny the allegations in paragraph 286.

287. Defendants deny the allegations in paragraph 287.

288. Defendants deny the allegations in paragraph 288.

COUNT XVI
LOSS OF CONSORTIUM

289. Defendants incorporate by reference their answers to each allegation as set forth in preceding paragraphs as if fully stated herein.

290. Paragraph 290 states a legal conclusion to which no response is required. To the extent a response is required, Defendants admit only that Plaintiffs refer to spouses and others with purported standing to assert claims arising from and/or damages resulting from the Devices as "Consortium Plaintiffs." Defendants are without knowledge or information sufficient to admit or deny Consortium Plaintiffs' relationship to Plaintiffs, and therefore deny the same. Defendants deny the remaining allegations in paragraph 290, specifically that any claims arose from and/or damages resulted from the Devices.

291. Defendants deny the allegations in paragraph 291.

292. Defendants deny the allegations in paragraph 292.

293. Defendants deny the allegations in paragraph 293.

294. Defendants deny the allegations in paragraph 294.

COUNT XVII
PUNITIVE DAMAGES

295. Defendants incorporate by reference their answers to each allegation as set forth in preceding paragraphs as if fully stated herein.

296. Defendants state that at certain times, Covidien sold certain Hernia Mesh Devices to health care providers in the United States. Defendants deny the remaining allegations in paragraph 296.

297. Defendants deny the allegations in paragraph 297.

298. Defendants state that at certain times, Covidien sold certain Hernia Mesh Devices to health care providers in the United States. Defendants deny the remaining allegations in paragraph 298.

299. Defendants deny the allegations in paragraph 299.

300. Defendants deny the allegations in paragraph 300.

301. Defendants deny the allegations in paragraph 301.

302. Defendants deny the allegations in paragraph 302.

303. Defendants deny the allegations in paragraph 303.

304. Defendants deny the allegations in paragraph 304.

PRAYER FOR RELIEF

Defendants deny that Plaintiffs are entitled to any of the relief set forth in the "PRAYER FOR RELIEF," or any relief whatsoever.

SEPARATE DEFENSES

Defendants assert the following defenses to Plaintiffs' Complaint. Defendants do not admit or acknowledge they bear the burden of proof and/or burden of persuasion with respect to any such defense. All of the following defenses are pled in the alternative, and none constitutes an admission that Defendants are liable to Plaintiffs, that Plaintiffs have been or will be injured or damaged in any way, or that Plaintiffs are entitled to any relief whatsoever. Defendants reserve

the right to: (i) rely upon any other defenses that may become apparent during fact or expert discovery in this matter; and (ii) amend this Answer to assert any such defenses.

FIRST DEFENSE
(Failure to State a Claim)

Plaintiffs' claims fail in whole or in part to state a claim against Defendants upon which relief can be granted under Rule 12 of the Federal Rules of Civil Procedure.

SECOND DEFENSE
(Denial)

Defendants deny the allegations in Plaintiffs' Complaint, and demand strict proof thereof.

THIRD DEFENSE
(Misuse of Product)

If Plaintiffs suffered damages, which Defendants deny, Defendants are not liable for damages that were caused by misuse or abuse of the product(s) or noncompliance with the products' instructions and/or warnings either by Plaintiffs or other persons. Such misuse was not reasonably foreseeable to Defendants.

FOURTH DEFENSE
(Product Alteration)

If Plaintiffs suffered damages, which Defendants deny, Defendants are not liable for any such damages that were caused by any modification, alteration, or change in the products at issue after the products left Defendants' possession and control.

FIFTH DEFENSE
(Assumption of the Risk)

If Plaintiffs have been damaged, which Defendants deny, any recovery by Plaintiffs is barred by the doctrines of assumption of risk or informed consent. Plaintiffs were fully aware of and informed about the nature of the products at issue and the risks and possible adverse effects,

if any, pertaining to their use and the surgical procedures allegedly performed. Additionally, all injuries, damages, or losses, if any, that Plaintiffs sustained arose from and were caused by risks of which Plaintiffs were aware. Plaintiffs accepted and assumed all risks. Accordingly, Plaintiffs' claims are barred in whole or in part, by the doctrines of assumption of risk or informed consent.

SIXTH DEFENSE
(Lack of Defect)

There were no defects in the products at issue, with the result that Plaintiffs are not entitled to recover against Defendants in this action.

SEVENTH DEFENSE
(Learned Intermediary Doctrine)

Plaintiff's claims are barred, in whole or in part, by the learned intermediary doctrine. Alternatively, Defendants deny any liability because Plaintiffs' treating physician(s), who are knowledgeable and sophisticated users over whom Defendants had no control, elected to use the products at issue with full knowledge of any foreseeable risks and dangers, if any, associated with the products and the precautions, if any, required to avoid those risks and dangers.

EIGHTH DEFENSE
(No Duty to Warn Plaintiff Directly)

Plaintiffs' claims are barred, in whole or in part, because Defendants had no duty to warn Plaintiffs directly in any respect including, but not limited to, possible dangers, if any, associated with any products at issue, and any products at issue were distributed with appropriate warnings to the medical community.

NINTH DEFENSE
(No Alternative Design)

If Plaintiffs have been damaged, which Defendants deny, any recovery by Plaintiffs is barred because any alleged defect(s) of the products at issue were not known and, in light of

existing, reasonably-available scientific and technical knowledge, could not have been known at the time the products at issue were designed, manufactured and/or sold. There is no practical or technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended function of Defendants' products. Plaintiffs' causes of action are barred, in whole or in part, by their failure to assert a feasible safer design for the products at issue.

TENTH DEFENSE
(Statute of Limitations)

Plaintiffs' claims are barred in whole or in part, by the applicable statutes of limitations and/or repose.

ELEVENTH DEFENSE
(Conformity with Industry Customs, Standards, and Regulations)

Plaintiffs' claims are barred because the methods, standards, and techniques utilized in designing, testing, manufacturing, assembling, distributing, marketing, labeling, and selling the products at issue, and in issuing warnings and instructions with respect to the use of such products, were in conformity with industry custom, usage, and standards and/or legislative, administrative, and regulatory standards.

TWELFTH DEFENSE
(State of Knowledge in the Field)

Plaintiffs' claims are barred because, based on the state of scientific, medical, and technical knowledge at the time the products were designed, tested, manufactured, assembled, distributed, marketed, labeled, sold, and issued with warning and instructions with respect to their use, the products at issue were reasonably safe for their normal and foreseeable use. If it should be proven that the products manufactured by Defendants were involved as alleged, then the state of medical

and scientific knowledge or published literature or other materials reflecting the state of medical and scientific knowledge at all times relevant hereto was such that Defendants neither knew nor could reasonable have known that the products at issue presented a foreseeable risk of harm in their normal and expected use.

THIRTEENTH DEFENSE
(Compliance with Federal and State Laws)

Defendants at all times conformed to the Federal Food, Drug and Cosmetic Act ("FDCA") and other pertinent statutes and regulations.

FOURTEENTH DEFENSE
(Causation – Pre-Existing Condition)

If Plaintiffs sustained injuries or losses as alleged in Plaintiffs' Complaint, which Defendants deny, such injuries or losses resulted from Plaintiffs' pre-existing and/or unrelated medical, genetic, and/or environmental conditions, diseases, or illnesses, subsequent medical conditions, natural courses of conditions, idiosyncratic reactions, and/or unusual susceptibility for which Defendants are not responsible and over which Defendants had no control.

FIFTEENTH DEFENSE
(Lack of Proximate Cause)

There is no causal connection between any alleged design or manufacturing defect, or alleged failure to warn of the risks associated with the products at issue, and Plaintiffs' alleged injuries and/or damages, with the result that Plaintiffs are not entitled to recover against Defendants in this action.

SIXTEENTH DEFENSE
(Causation – Superseding/Intervening Cause)

If Plaintiffs have sustained injuries or losses as alleged in Plaintiffs' Complaint, which Defendants deny, such damages were caused in whole or in part through the operation of one or

more unforeseeable, independent, intervening, and/or superseding events for which Defendants are not legally responsible.

SEVENTEENTH DEFENSE
(Causation – Not a Substantial Cause)

Any conduct allegedly causing liability on the part of Defendants is not a substantial cause or factor of any potential or actual injury or damage alleged by Plaintiffs.

EIGHTEENTH DEFENSE
(Third Party Acts)

If Plaintiffs have sustained injuries or losses as alleged in Plaintiffs' Complaint, which Defendants deny, such injuries and losses were caused by the actions and independent knowledge of such persons not having real or apparent authority to take said actions on behalf of Defendants and over whom Defendants had no control and for whom Defendants may not be held accountable. If they were the agents of Defendants, which Defendants expressly deny, they were acting outside the scope of employment. Accordingly, Defendants deny liability for any damages arising out of the independent actions, independent knowledge, and awareness of such parties, third persons, or independent contractors.

NINETEENTH DEFENSE
(Failure to Exercise Reasonable Care and Diligence)

Any recovery by Plaintiffs should not include alleged damages that Plaintiffs could have avoided by reasonable care and diligence.

TWENTIETH DEFENSE
(Failure to Mitigate)

If Plaintiffs sustained injuries or losses, which Defendants deny, Plaintiffs' claims are barred, in whole or in part, by their failure to exercise reasonable care and diligence to mitigate their alleged damages.

TWENTY-FIRST DEFENSE
(Failure to Join Indispensable Parties)

Plaintiffs may have failed to join indispensable parties, in which case it may not be possible to accord complete relief to the parties that are already parties to this action. Plaintiffs' failure to join indispensable parties could result in prejudice.

TWENTY-SECOND DEFENSE
(Preemption)

Plaintiffs' claims are expressly and/or impliedly preempted.

TWENTY-THIRD DEFENSE
(Equitable Doctrines)

The claims asserted in Plaintiffs' Complaint are barred, in whole or in part, by the doctrines of consent, waiver, estoppel, release, merger, bar, res judicata, collateral estoppel, discharge, accord and satisfaction, unclean hands, and laches.

TWENTY-FOURTH DEFENSE
(Settlement of Claims)

To the extent Plaintiffs have settled or will in the future settle with any person or entity with respect to the injuries asserted in Plaintiffs' Complaint, Defendants' liability, if any, should be reduced accordingly. Plaintiffs' claims are also subject to an offset in the amount of any reimbursement received as a result of any insurance, Medicaid coverage, other health benefit plan, or any amount paid for by any insurance or other health benefits plan.

TWENTY-FIFTH DEFENSE
(Credit for Settlement)

Defendants are entitled to any credit or set-off for any settlement of claims for alleged injuries and damages made by Plaintiffs with any other person or entity. Defendants are further

entitled to a set-off for the total of all amounts paid to Plaintiffs from all collateral sources and the amounts that Plaintiffs recover from all other sources.

TWENTY-SIXTH DEFENSE
(Proportionate Fault)

In the event it is determined that Plaintiffs are entitled to recover against Defendants, recovery should be reduced in proportion to the degree or percentage of negligence or fault attributable to Plaintiffs, third parties, or other persons, including any parties immune because bankruptcy renders them immune from further litigation, as well as any non-parties with whom Plaintiffs have settled or may settle in the future.

TWENTY-SEVENTH DEFENSE
(Contribution and Indemnification)

Plaintiffs' claims may be barred, in whole or in part, because Plaintiffs' injuries, if any, were caused, in whole or in part, by the negligence, fault, or wrongful conduct of Plaintiffs or by third parties, over whom Defendants had and have no control or right of control and for whom they are not responsible, and Plaintiffs' claims may be barred or limited by the doctrine of contributory negligence. If Plaintiffs recover from Defendants, Defendants are entitled to contribution and/or indemnification, either in whole or in part, from all persons or entities whose negligence or fault proximately caused or contributed to Plaintiffs' alleged damages.

TWENTY-EIGHTH DEFENSE
(Comparative Negligence)

Any liability that might otherwise be imposed on Defendants are subject to reduction by the application of the doctrine of comparative negligence.

TWENTY-NINTH DEFENSE
(Spoliation of Evidence)

If Plaintiffs or any other party failed to retain, maintain, and keep as evidence Defendants' product or any other documents related to Defendants' products, Defendants may raise the legal doctrine of spoliation.

THIRTIETH DEFENSE
(Good Faith)

Discovery or investigation may reveal that Plaintiffs' claims are barred, in whole or in part, because Defendants acted reasonably and in good faith at all material times, based on all relevant facts and circumstances known by Defendants at the time they allegedly acted or failed to act.

THIRTY-FIRST DEFENSE
(Protected Speech)

Plaintiffs' claims are barred, in whole or in part, because Defendants' advertisements and labeling with respect to its products were not false or misleading, and, therefore, constitute protected commercial speech under the First Amendment of the Unites States Constitution.

THIRTY-SECOND DEFENSE
(Failure to Plead with Particularity)

Plaintiffs' fraud claims are barred for failure to plead them with particularity or specificity.

THIRTY-THIRD DEFENSE
(No Reliance)

Plaintiffs' claims are barred because there was no reliance on representations (if any) made by Defendants.

THIRTY-FOURTH DEFENSE
(No Misrepresentation)

Plaintiffs' claims are barred because any alleged misrepresentation on which Plaintiffs relied did not constitute a misrepresentation of material facts.

THIRTY-FIFTH DEFENSE
(No Actionable Misrepresentation)

Plaintiffs' purported allegations of misrepresentation fail to state a claim for which relief may be granted. To the extent Plaintiffs' claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred pursuant to *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

THIRTY-SIXTH DEFENSE
(No Reliance on Alleged Misrepresentation)

Plaintiffs' claims are barred by the failure of Plaintiffs or Plaintiffs' physicians to reasonably or justifiably rely on any alleged fraud, misrepresentation, concealment, or omission by Defendants.

THIRTY-SEVENTH DEFENSE
(Excluded Warranties)

Plaintiffs' claims are barred in whole or in part because any warranties, if made, are excluded through course of dealing, course of performance, and/or usage of trade.

THIRTY-EIGHTH DEFENSE
(Expired Warranty)

Defendants assert the defenses of expiration, limitation, and exclusion to any applicable express or implied warranty, if any be proven.

THIRTY-NINTH DEFENSE
(Disclaimed Warranty and No Timely Notice of Breach of Warranty)

Defendants deny making any express or implied warranties to Plaintiffs. In the alternative, Defendants allege that any and all warranties that may form a basis for Plaintiffs' claims were adequately disclaimed. In the alternative, Plaintiffs failed to give timely notice of breach of

warranty claims, pursuant to applicable state law, and Plaintiffs are therefore barred from any recovery in this action.

FORTIETH DEFENSE

(No Participation in Alleged Misrepresentations)

Defendants did not participate in, authorize, ratify, or benefit from the alleged misrepresentations or wrongful acts that are asserted in the Complaint.

FORTY-FIRST DEFENSE

(Claims Barred by Restatement of Torts: Useful and Desirable Devices)

Plaintiffs' claims are barred by the provisions of the Restatement (Second) of Torts, Section 402A, Comment (k), and relevant case law upholding and applying those provisions, as well as comparable provisions of the Restatement (Third) of Torts. Plaintiffs' claims are barred because the medical devices in question are useful and desirable, and any risk claimed by Plaintiffs with its use and any alleged injuries, to the extent they exist, were unavoidable.

FORTY-SECOND DEFENSE

(Claims Barred by Restatement of Torts: Neither Defective nor Unreasonably Dangerous)

Plaintiffs' claims are barred by the provisions of the Restatement (Second) of Torts, Section 402A, Comment (j), and relevant case law upholding and applying those provisions, as well as comparable provisions of the Restatement (Third) of Torts. The products at issue are neither defective nor unreasonably dangerous because at all material times they were reasonably safe, and the warnings and instructions accompanying the products at the time of the occurrence or injuries alleged by Plaintiffs were legally adequate.

FORTY-THIRD DEFENSE

(Causation Required)

To the extent Plaintiffs' claims are based on a theory providing for liability without proof of causation, the claims violate Defendants' rights under the United States Constitution.

FORTY-FOURTH DEFENSE
(Risk-Utility)

Plaintiffs' claims are barred because the risks, if any, associated with the use of Defendants' products are outweighed by the devices' utility.

FORTY-FIFTH DEFENSE
(Claims Do Not Benefit the Public)

Plaintiffs' claims for violation of consumer protection statutes may fail as a matter of law because the claims do not benefit the public.

FORTY-SIXTH DEFENSE
(No Private Cause of Action for Money Damages for Consumer Protection Claims)

Plaintiffs' claims for violation of consumer protection statutes may fail as a matter of law because the relevant statutes do not provide a private cause of action for monetary damages.

FORTY-SEVENTH DEFENSE
(Statutory Notice Required)

Plaintiffs' claims may be barred, in whole or in part, because Plaintiffs failed to give the required statutory notice.

FORTY-EIGHTH DEFENSE
(Reasonable Care in Design)

Defendants used reasonable care in designing the hernia mesh products at issue.

FORTY-NINTH DEFENSE
(Adequate Warnings)

Defendants provided reasonably adequate warnings/instructions for hernia mesh products to those who used the product as intended or in a way that the Defendants reasonably anticipated.

FIFTIETH DEFENSE
(Privity Required)

Plaintiffs' breach of warranty claims may be barred due to a lack of privity.

FIFTY-FIRST DEFENSE
(Loss of Consortium Claims Not Actionable)

One or more of Plaintiffs' claims for loss of consortium may not be recognized by the applicable state law.

FIFTY-SECOND DEFENSE
(No Standing)

One of more of Plaintiffs' claims may be barred, in whole or in part, by lack of standing.

FIFTY-THIRD DEFENSE
(Limited Damages in Wrongful Death Claims)

With respect to any claims for wrongful death, Plaintiffs' damages are limited to those provided by statute.

FIFTY-FOURTH DEFENSE
(Act of God)

If Plaintiff sustained the injuries or incurred the expenses alleged, they may have been caused, in whole or in part, by operation of nature or by an act of God or other intervening causes.

FIFTY-FIFTH DEFENSE
(Benefits Received)

Notwithstanding Plaintiffs' claims, Plaintiffs received all or substantially all of the benefit from Defendants' hernia mesh products that Plaintiffs hoped and intended to receive, and, to that extent, any damages and/or restitution that Plaintiffs might be entitled to recover from Defendants must be correspondingly reduced.

FIFTY-SIXTH DEFENSE
(Product Liability Acts)

Defendants are entitled to the benefit of, and hereby claim, all defenses and presumptions available pursuant to any applicable Product Liability Act.

FIFTY-SEVENTH DEFENSE
(Reservation of Rights: State Law)

Defendants reserve the right to assert any and all available affirmative defenses under the laws of any State, Commonwealth or District whose laws are or later become relevant in the course of this litigation.

FIFTY-EIGHTH DEFENSE
(Reservation of Rights: Investigation and Discovery)

Defendants reserve the right to supplement this Answer and Affirmative Defenses with additional defenses that become available or apparent during the course of investigation, preparation, or discovery and to amend their Answer accordingly.

FIFTY-NINTH DEFENSE
(Punitive Damages Not an Independent Cause of Action)

Plaintiffs' claim for punitive damages fails as a matter of law because it is well settled that punitive damages are not an independent cause of action.

SIXTIETH DEFENSE
(No Recovery for Punitive Damages)

No act or omission by Defendants was malicious, willful, wanton, reckless, grossly negligent, or intentional and, therefore, any award of punitive damages is barred.

SIXTY-FIRST DEFENSE
(Punitive Damages Unconstitutional)

Plaintiffs' claims for punitive damages are in violation of Defendants' state and federal constitutional rights, including Defendants' rights under the Due Process Clause of the Fifth and Fourteenth Amendments of the United States Constitution and similar provisions of the Constitution, law, public policies, and statutes of any State or Commonwealth of the United States whose laws are or later become relevant in the course of this litigation.

SIXTY-SECOND DEFENSE

(Punitive Damages: Standards and Limits)

Plaintiffs' claims for punitive damages are in violation of Defendants' rights under the Due Process Clause of the Fifth and Fourteenth Amendments of the United States Constitution; the Excessive Fines Clause of the Eighth Amendment of the United States Constitution; the Double Jeopardy Clause of the Fifth Amendment of the United States Constitution; and similar provisions in the Constitution, laws, public policies, and statutes of any State or Commonwealth of the United States whose laws are or later become relevant in the course of this litigation, insofar as such damages are awarded by a jury or other fact-finder that: (a) is not provided with a standard of sufficient clarity for determining the appropriateness, and the appropriate size, of a punitive damages award; (b) is not adequately and clearly instructed on the limits of punitive damages imposed by the applicable principles of deterrence and punishment; (c) is not expressly prohibited from awarding punitive damages, or determining the amount of an award of punitive damages, in whole or in part, on the basis of invidiously discriminatory characteristics, including the corporate status, wealth, or state of residence of Defendants; (d) is permitted to award punitive damages under a standard for determining liability for such damages that is vague and arbitrary and does not define with sufficient clarity the conduct or mental state that makes punitive damages permissible; and/or (e) is not subject to trial court and appellate judicial review for reasonableness and the furtherance of legitimate purposes on the basis of objective standards.

SIXTY-THIRD DEFENSE

(Punitive Damages: Liability and Conduct)

Plaintiffs' claims for punitive damages are in violation of Defendants' rights under the Due Process Clause of the Fifth and Fourteenth Amendments of the United States Constitution; the Excessive Fines Clause of the Eighth Amendment of the United States Constitution; the Double

Jeopardy Clause of the Fifth Amendment of the United States Constitution; and similar provisions in the Constitution, laws, public policies, and statutes of any State or Commonwealth of the United States whose laws are or later become relevant in the course of this litigation, insofar as such damages are (a) imposed and determined without bifurcating the trial and trying all punitive damages issues only if and after the liability of Defendants has been found on the merits, and/or (b) imposed and determined based on anything other than Defendants' conduct in connection with the sale of certain hernia mesh products alleged in this litigation, or in any other way subjecting Defendants to impermissible multiple punishments for the same alleged wrong.

JURY DEMAND

Defendants demand a trial by jury for all matters so triable.

WHEREFORE, Defendants pray for relief and judgment against Plaintiffs as follows:

A. That Plaintiffs take nothing by reason of the Complaint;

B. That this action be dismissed with prejudice;

C. That Defendants recover attorneys' fees and costs incurred herein; and

Such further and other relief as the Court deems just and proper.

Dated: March 15, 2023

Respectfully submitted,

/s/ Jessica C. Wilson

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CERTIFICATE OF SERVICE

I hereby certify that on this 15th day of March 2023, I electronically filed the foregoing using the CM/ECF system, which will send a notice of this electronic filing to all counsel of record.

/s/ Jessica C. Wilson